UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

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BRISTOL-MYERS SQUIBB COMPANY)
Corporate Headquarters 345 Park Avenue New York, NY 10154, and KOSAN BIOSCIENCES INC. P.O. Box 4000 Princeton, NJ 08543-4000,)))))))))))))
Plaintiffs, v. JOHN J. DOLL, in his official capacity as Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office Office of General Counsel United States Patent and Trademark Office P.O. Box 15667, Arlington, VA 22215 Madison Building East, Room 10B20 600 Dulany Street, Alexandria, VA 22314, Defendant.	Case: 1:09-cv-01330 Assigned To: Kessler, Gladys Assign. Date: 7/17/2009 Description: Admn. Agency Review))))))))))))))))))

COMPLAINT

Plaintiffs Bristol-Myers Squibb Company ("BMS") and Kosan Biosciences Inc.

("Kosan"), for their Complaint against the John J. Doll, hereby alleges as follows:

Nature of Action

- 1. This is an action by the assignees of 20 United States patents seeking review of the patent term adjustments granted by the Director of the United States Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. § 154(b).
- 2. All of the challenged PTO patent term adjustment determinations relied on an erroneous interpretation of 35 U.S.C. § 154(b) that this Court rejected in Wyeth v. Dudas, 580 F. Supp. 2d 138 (D.D.C. 2008), appeal pending No. 2009-1120 (Fed. Cir.).

Parties

- 3. Plaintiff BMS is a Delaware corporation with its principal place of business in New York.
- 4. Plaintiff Kosan is a Delaware corporation with its principal place of business in New Jersey. Kosan is a wholly owned subsidiary of BMS.
- 5. Defendant John J. Doll is sued in his official capacity as Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the PTO. The Director of the PTO is designated by statute as the official responsible for determining the period of patent term adjustments, see 35 U.S.C. § 154(b)(3), and as the proper defendant in a suit seeking review of such determinations, see id. § 154(b)(4)(A).

Jurisdiction and Venue

- 6. This action arises under 35 U.S.C. § 154 and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.
- 7. This Court has subject-matter jurisdiction over this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1361; 35 U.S.C. §§ 154(b)(4)(A); and 5 U.S.C. §§ 701-706.

8. Venue is proper in this Court under 35 U.S.C. § 154(b)(4)(A).

Background

- 9. Under 35 U.S.C. § 154(a)(2), a successful patent applicant is entitled to a 20-year patent term beginning on the date its application was first filed with the PTO. Because this period starts to run with the filing of the application rather than with the grant of the patent, any delay in the PTO's processing of an application reduces the applicant's effective patent term.
- 10. To prevent such administrative delays from causing unfair losses of patent protection, Congress directed the PTO to grant successful applicants upward adjustments of their patent terms to compensate for three categories of processing delay by the PTO. Those three categories, set forth in 35 U.S.C. § 154(b)(1)(A), (B), and (C), are known as "A delays," "B delays," and "C delays," respectively. Only "A delays" and "B delays" are at issue in this case.
- "A delays" occur when the PTO fails to take one of several specified actions within a particular time period—for example, if the PTO does not "issue a patent within 4 months after the date on which the issue fee was paid ... and all other outstanding requirements were satisfied." 35 U.S.C. § 154(b)(1)(A)(iv). The statute provides that "the term of the patent shall be extended by 1 day for each day after the end of the period specified ... until the action described ... is taken." *Id.* § 154(b)(1)(A).
- 12. "B delays" occur when the PTO fails to issue a patent within 3 years of the filing of the patent application, excluding certain periods of delay attributable to the applicant.

 35 U.S.C. § 154(b)(1)(B). As with "A delays," the statute provides for a day-for-day patent term adjustment to compensate for any "B delays": "[T]he term of the patent shall be extended by 1 day for each day after the end of that 3-year period until the patent is issued." *Id*.

- 13. In calculating a patent term adjustment, however, Congress directed that overlapping periods of "A delay" and "B delay" may not be double-counted: "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). The dispute in this case concerns the proper interpretation of this provision.
- 14. The PTO has taken the position that whenever an application is subject to both "A delay" and "B delay," those periods *always* "overlap" within the meaning of § 154(b)(2)(A)—even if they occur on different calendar days. *See* 69 Fed. Reg. 34,283 (June 21, 2004). The result of this interpretation is that an applicant is entitled to an adjustment equal to *either* the "A delay" or the "B delay," whichever is longer, but never to an adjustment equal to the "A delay" *plus* the "B delay."
- 15. This Court rejected the PTO's interpretation of § 154(b)(2)(A) in Wyeth v. Dudas, 580 F. Supp. 2d 138 (D.D.C. 2008). Giving the words of the statute their plain meaning, the Court observed that "[t]he only way that periods of time can 'overlap' is if they occur on the same day." Id. at 141. The Court thus held that "[i]f an 'A delay' occurs on one calendar day and a 'B delay' occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day." Id. at 141-142.
- 16. Notwithstanding the Court's holding in Wyeth, the PTO has adhered to its erroneous interpretation of § 152(b)(2)(A). The agency thus continues to determine patent term adjustments in a manner that is contrary to the statute.
- 17. The PTO relied on this improper method in calculating the patent term adjustment applicable to each of the patents at issue in this case. If those adjustments had instead been

calculated in accordance with this Court's decision in *Wyeth*, plaintiffs would have received the longer adjustments that they now seek in this suit.

18. This Complaint is timely filed under 35 U.S.C. § 154(b)(4)(A).

COUNT I

- 19. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 20. BMS is the assignee of United States Patent No. 7,517,991 ("the '991 patent").
- 21. The application for this patent was filed on October 11, 2005, and the patent issued on April 14, 2009.
- 22. The patent term adjustment determined by the Director and currently reflected on the patent is 364 days.
- 23. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.
- 24. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 364 days.
- 25. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 185 days.
- 26. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 27. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."
- 28. The total period of PTO delay in the processing of the patent application is therefore 549 days, which is equal to the "A delay" (364 days) plus the "B delay" (185 days).

- 29. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 0 days.
- 30. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 549 days.
- 31. On May 18, 2009, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 549 days. The Request for Reconsideration remains pending.
- 32. The PTO's determination of the patent term extension for the '991 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT II

- 33. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 34. BMS is the assignee of United States Patent No. 7,504,211 ("the '211 patent").
- 35. The application for this patent was filed on August 26, 2003, and the patent issued on March 17, 2009.
- 36. The patent term adjustment determined by the Director and currently reflected on the patent is 0 days.
- 37. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.

- 38. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 255 days.
- 39. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 263 days.
- 40. None of the days of "A delays" occurred on the same calendar day as the properly calculated "B delays."
- 41. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, none of the days of "A delays" overlap with "B delays."
- 42. The total period of PTO delay in the processing of the patent application is therefore 518 days, which is equal to the "A delay" (255 days) plus the "B delay" (263 days).
- 43. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 313 days.
- 44. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 205 days, which is equal to the total period of PTO delay (518 days) minus the period of applicant delay (313 days).
- 45. On May 14, 2009, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the PTO's calculation of the patent term adjustment was incorrect. Although the request indicated that the proper period of patent term adjustment was 858 days, BMS has now determined that the proper period of adjustment is 205 days. The Request for Reconsideration remains pending.

46. The PTO's determination of the patent term extension for the '211 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT III

- 47. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 48. BMS is the assignee of United States Patent No. 7,482,372 ("the '372 patent").
- 49. The application for this patent was filed on March 30, 2005, and the patent issued on January 27, 2009.
- 50. The patent term adjustment determined by the Director and currently reflected on the patent is 590 days.
- 51. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in *Wyeth v. Dudas*.
- 52. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 590 days.
- 53. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 303 days.
- 54. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 55. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."
- 56. The total period of PTO delay in the processing of the patent application is therefore 893 days, which is equal to the "A delay" (590 days) plus the "B delay" (303 days).

- 57. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 0 days.
- 58. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 893 days.
- On March 10, 2009, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 893 days. The PTO denied that request on May 19, 2009.
- 60. The PTO's determination of the patent term extension for the '372 patent—in both its initial determination and in its denial of the Request for Reconsideration—was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT IV

- 61. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 62. BMS is the assignee of United States Patent No. 7,479,496 ("the '496 patent").
- 63. The application for this patent was filed on February 17, 2005, and the patent issued on January 20, 2009.
- 64. The patent term adjustment determined by the Director and currently reflected on the patent is 550 days.
- 65. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in *Wyeth v. Dudas*.

- 66. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 550 days.
- 67. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 338 days.
- 68. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 69. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."
- 70. The total period of PTO delay in the processing of the patent application is therefore 888 days, which is equal to the "A delay" (550 days) plus the "B delay" (338 days).
- 71. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 0 days.
- 72. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 888 days.
- 73. On February 11, 2009, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 888 days. The Request for Reconsideration remains pending.
- 74. The PTO's determination of the patent term extension for the '496 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT V

- 75. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 76. BMS is the assignee of United States Patent No. 7,470,713 ("the '713 patent").
- 77. The application for this patent was filed on February 18, 2005, and the patent issued on December 30, 2008.
- 78. The patent term adjustment determined by the Director and currently reflected on the patent is 560 days.
- 79. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in *Wyeth v. Dudas*.
- 80. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 560 days.
- 81. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 316 days.
- 82. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 83. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wveth, no days of "A delays" overlap with "B delays."
- 84. The total period of PTO delay in the processing of the patent application is therefore 876 days, which is equal to the "A delay" (560 days) plus the "B delay" (316 days).
- 85. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 0 days.

- 86. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 876 days.
- 87. On January 14, 2009, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 876 days. The PTO denied that request on March 30, 2009.
- 88. The PTO's determination of the patent term extension for the '713 patent—in both its initial determination and in its denial of the Request for Reconsideration—was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT VI

- 89. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 90. BMS is the assignee of United States Patent No. 7,470,712 ("the '712 patent").
- 91. The application for this patent was filed on January 19, 2005, and the patent issued on December 30, 2008.
- 92. The patent term adjustment determined by the Director and currently reflected on the patent is 508 days.
- 93. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.
- 94. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 509 days.
- 95. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 346 days.

- 96. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 97. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."
- 98. The total period of PTO delay in the processing of the patent application is therefore 855 days, which is equal to the "A delay" (509 days) plus the "B delay" (346 days).
- 99. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 1 day.
- 100. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 854 days, which is equal to the total period of PTO delay (855 days) minus the period of applicant delay (1 day).
- 101. On January 7, 2009, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 854 days. The PTO denied that request on May 18, 2009.
- 102. The PTO's determination of the patent term extension for the '712 patent—in both its initial determination and in its denial of the Request for Reconsideration—was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT VII

103. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.

- 104. BMS is the assignee of United States Patent No. 7,459,562 ("the '562 patent").
- 105. The application for this patent was filed on April 21, 2005, and the patent issued on December 2, 2008.
- 106. The patent term adjustment determined by the Director and currently reflected on the patent is 391 days.
- 107. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.
- 108. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 429 days.
- 109. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 225 days.
- 110. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 111. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in .

 Wyeth, no days of "A delays" overlap with "B delays."
- 112. The total period of PTO delay in the processing of the patent application is therefore 654 days, which is equal to the "A delay" (429 days) plus the "B delay" (225 days).
- 113. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 38 days.

- 114. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 616 days, which is equal to the total period of PTO delay (654 days) minus the period of applicant delay (38 days).
- 115. On December 3, 2008, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 654 days. The Request for Reconsideration remains pending.
- 116. The PTO's determination of the patent term extension for the '562 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT VIII

- 117. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 118. BMS is the assignee of United States Patent No. 7,455,835 ("the '835 patent").
- 119. The application for this patent was filed on July 2, 2001, and the patent issued on November 25, 2008.
- 120. The patent term adjustment determined by the Director and currently reflected on the patent is 0 days.
- 121. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.
- 122. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 394 days.
- 123. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 521 days.

- 124. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 125. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."
- 126. The total period of PTO delay in the processing of the patent application is therefore 915 days, which is equal to the "A delay" (394 days) plus the "B delay" (521 days).
- 127. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 523 days.
- 128. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 392 days, which is equal to the total period of PTO delay (915 days) minus the period of applicant delay (523 days).
- 129. On January 23, 2009, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 392 days. The Request for Reconsideration remains pending.
- 130. The PTO's determination of the patent term extension for the '835 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT IX

- 131. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 132. BMS is the assignee of United States Patent No. 7,453,002 ("the '002 patent").

- 133. The application for this patent was filed on June 13, 2005, and the patent issued on November 18, 2008.
- 134. The patent term adjustment determined by the Director and currently reflected on the patent is 289 days.
- 135. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in *Wyeth v. Dudas*.
- 136. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 302 days.
- 137. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 158 days.
- 138. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 139. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."
- 140. The total period of PTO delay in the processing of the patent application is therefore 460 days, which is equal to the "A delay" (302 days) plus the "B delay" (158 days).
- 141. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 13 days.
- 142. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 447 days, which is equal to the total period of PTO delay (460 days) minus the period of applicant delay (13 days).

143. On November 20, 2008, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 447 days. The Request for Reconsideration remains pending.

The PTO's determination of the patent term extension for the '002 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT X

- 144. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 145. BMS is the assignee of United States Patent No. 7,452,678 ("the '678 patent").
- 146. The application for this patent was filed on June 22, 2004, and the patent issued on November 18, 2008.
- 147. The patent term adjustment determined by the Director and currently reflected on the patent is 456 days.
- 148. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.
- 149. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 571 days.
- 150. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 515 days.
 - 151. Only 87 days of "A delays" occurred on the same calendar day as the "B delays."
- 152. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, only 87 days of "A delays" overlap with "B delays."

- 153. The total period of PTO delay in the processing of the patent application is therefore 999 days, which is equal to the "A delay" (571 days) plus the "B delay" (515 days) minus the period of overlap (87 days).
- 154. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 115 days.
- 155. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 884 days, which is equal to the total period of PTO delay (999 days) minus the period of applicant delay (115 days).
- 156. On December 8, 2008, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 884 days. The Request for Reconsideration remains pending.
- 157. The PTO's determination of the patent term extension for the '678 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT XI

- 158. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 159. Kosan is the assignee of United States Patent No. 7,446,196 ("the '196 patent").
- 160. The application for this patent was filed on June 1, 2005, and the patent issued on November 4, 2008.
- 161. The patent term adjustment determined by the Director and currently reflected on the patent is 479 days.

- 162. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.
- 163. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 507 days.
- 164. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 156 days.
- 165. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 166. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."
- 167. The total period of PTO delay in the processing of the patent application is therefore 663 days, which is equal to the "A delay" (507 days) plus the "B delay" (156 days).
- 168. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 28 days.
- 169. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 635 days, which is equal to the total period of PTO delay (663 days) minus the period of applicant delay (28 days).
- 170. On November 24, 2008, Kosan filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 635 days. The PTO denied that request on March 31, 2009.

171. The PTO's determination of the patent term extension for the '196 patent—in both its initial determination and in its denial of the Request for Reconsideration—was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT XII

- 172. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 173. BMS is the assignee of United States Patent No. 7,435,808 ("the '808 patent").
- 174. The application for this patent was filed on June 23, 2004, and the patent issued on October 14, 2008.
- 175. The patent term adjustment determined by the Director and currently reflected on the patent is 282 days.
- 176. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in *Wyeth v. Dudas*.
- 177. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 478 days.
- 178. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 479 days.
 - 179. Only 45 days of "A delays" occurred on the same calendar day as the "B delays."
- 180. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, only 45 days of "A delays" overlap with "B delays."
- 181. The total period of PTO delay in the processing of the patent application is therefore 912 days, which is equal to the "A delay" (478 days) plus the "B delay" (479 days) minus the period of overlap (45 days).

- 182. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 197 days. In fact, however, the period of applicant delay was only 192 days.
- 183. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 720 days, which is equal to the total period of PTO delay (912 days) minus the period of applicant delay (192 days).
- 184. On October 31, 2008, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision and using the correct period of applicant delay, the proper period of patent term adjustment was 720 days. The Request for Reconsideration remains pending.
- 185. The PTO's determination of the patent term extension for the '808 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT XIII

- 186. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 187. BMS is the assignee of United States Patent No. 7,432,373 ("the '373 patent").
- 188. The application for this patent was filed on June 24, 2005, and the patent issued on October 7, 2008.
- 189. The patent term adjustment determined by the Director and currently reflected on the patent is 369 days.

- 190. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in *Wyeth v. Dudas*.
- 191. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 369 days.
- 192. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 105 days.
- 193. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 194. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."
- 195. The total period of PTO delay in the processing of the patent application is therefore 474 days, which is equal to the "A delay" (369 days) plus the "B delay" (105 days).
- 196. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 0 days.
- 197. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 474 days.
- 198. On November 17, 2008, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 474 days. The PTO denied that request on June 16, 2009.

199. The PTO's determination of the patent term extension for the '373 patent—in both its initial determination and in its denial of the Request for Reconsideration—was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT XIV

- 200. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 201. BMS is the assignee of United States Patent No. 7,432,271 ("the '271 patent").
- 202. The application for this patent was filed on September 1, 2004, and the patent issued on October 7, 2008.
- 203. The patent term adjustment determined by the Director and currently reflected on the patent is 523 days.
- 204. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.
- 205. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 523 days.
- 206. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 402 days.
 - 207. Only 79 days of "A delays" occurred on the same calendar day as the "B delays."
- 208. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, only 79 days of "A delays" overlap with "B delays."
- 209. The total period of PTO delay in the processing of the patent application is therefore 846 days, which is equal to the "A delay" (523 days) plus the "B delay" (402 days) minus the period of overlap (79 days).

- 210. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 0 days.
- 211. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 846 days.
- 212. On October 30, 2008, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 846 days. The Request for Reconsideration remains pending.
- 213. The PTO's determination of the patent term extension for the '271 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT XV

- 214. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 215. BMS is the assignee of United States Patent No. 7,432,267 ("the '267 patent").
- 216. The application for this patent was filed on June 28, 2005, and the patent issued on October 7, 2008.
- 217. The patent term adjustment determined by the Director and currently reflected on the patent is 370 days.
- 218. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.
- 219. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 381 days.

- 220. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 101 days.
- 221. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 222. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."
- 223. The total period of PTO delay in the processing of the patent application is therefore 482 days, which is equal to the "A delay" (381 days) plus the "B delay" (101 days).
- 224. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 11 days.
- 225. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 471 days, which is equal to the total period of PTO delay (482 days) minus the period of applicant delay (11 days).
- 226. On October 29, 2008, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 471 days. The Request for Reconsideration remains pending.
- 227. The PTO's determination of the patent term extension for the '267 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT XVI

- 228. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 229. BMS is the assignee of United States Patent No. 7,429,611 ("the '611 patent").
- 230. The application for this patent was filed on September 21, 2005, and the patent issued on September 30, 2008.
- 231. The patent term adjustment determined by the Director and currently reflected on the patent is 236 days.
- 232. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.
- 233. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 236 days.
- 234. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 9 days.
- 235. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 236. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."
- 237. The total period of PTO delay in the processing of the patent application is therefore 245 days, which is equal to the "A delay" (236 days) plus the "B delay" (9 days).
- 238. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 0 days.

- 239. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 245 days.
- 240. On October 30, 2008, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 245 days. The Request for Reconsideration remains pending.
- 241. The PTO's determination of the patent term extension for the '611 patent was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT XVII

- 242. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 243. BMS is the assignee of United States Patent No. 7,429,604 ("the '604 patent").
- 244. The application for this patent was filed on June 13, 2005, and the patent issued on September 30, 2008.
- 245. The patent term adjustment determined by the Director and currently reflected on the patent is 431 days.
- 246. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.
- 247. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 431 days.
- 248. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 109 days.
- 249. None of the days of "A delays" occurred on the same calendar day as the "B delays."

- 250. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."
- 251. The total period of PTO delay in the processing of the patent application is therefore 540 days, which is equal to the "A delay" (431 days) plus the "B delay" (109 days).
- 252. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 0 days.
- 253. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 540 days.
- 254. On October 27, 2008, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 540 days. The PTO denied that request on June 9, 2009.
- 255. The PTO's determination of the patent term extension for the '604 patent—in both its initial determination and in its denial of the Request for Reconsideration—was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT XVIII

- 256. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 257. Kosan is the assignee of United States Patent No. 7,427,493 ("the '493 patent").
- 258. The application for this patent was filed on June 30, 2003, and the patent issued on September 23, 2008.

- 259. The patent term adjustment determined by the Director and currently reflected on the patent is 690 days.
- 260. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.
- 261. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 473 days.
- 262. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 816 days.
- 263. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 264. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."
- 265. The total period of PTO delay in the processing of the patent application is therefore 1289 days, which is equal to the "A delay" (473 days) plus the "B delay" (816 days).
- 266. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 126 days.
- 267. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 1,163 days, which is equal to the total period of PTO delay (1289 days) minus the period of applicant delay (126 days).
- 268. On October 29, 2008, Kosan filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request

demonstrated that in light of the Wyeth decision, the proper period of patent term adjustment was 1,163 days. The PTO denied that request on April 23, 2009.

269. The PTO's determination of the patent term extension for the '493 patent—in both its initial determination and in its denial of the Request for Reconsideration—was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT XIX

- 270. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 271. BMS is the assignee of United States Patent No. 7,417,063 ("the '063 patent").
- •272. The application for this patent was filed on April 11, 2005, and the patent issued on August 26, 2008.
- 273. The patent term adjustment determined by the Director and currently reflected on the patent is 500 days.
- 274. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.
- 275. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 500 days.
- 276. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 137 days.
- 277. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 278. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."

- 279. The total period of PTO delay in the processing of the patent application is therefore 637 days, which is equal to the "A delay" (500 days) plus the "B delay" (137 days).
- 280. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 0 days.
- 281. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 637 days.
- 282. On October 24, 2008, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 637 days. The PTO denied that request on May 6, 2009.
- 283. The PTO's determination of the patent term extension for the '063 patent in both its initial determination and in its denial of the Request for Reconsideration—was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

COUNT XX

- 284. Plaintiffs incorporate paragraphs 1-18 as if fully set forth herein.
- 285. BMS is the assignee of United States Patent No. 7,417,040 ("the '040 patent").
- 286. The application for this patent was filed on February 25, 2005, and the patent issued on August 26, 2008.
- 287. The patent term adjustment determined by the Director and currently reflected on the patent is 318 days.

- 288. The Director's determination of the patent term adjustment was incorrect because it was based on the erroneous statutory interpretation that this Court rejected in Wyeth v. Dudas.
- 289. Under 35 U.S.C. § 154(b)(1)(A), the application for the patent was subject to "A delays" of 318 days.
- 290. Under 35 U.S.C. § 154(b)(1)(B), the application was also subject to a "B delay" of 183 days.
- 291. None of the days of "A delays" occurred on the same calendar day as the "B delays."
- 292. Thus, under the correct interpretation of § 154(b)(2)(A) set forth by this Court in Wyeth, no days of "A delays" overlap with "B delays."
- 293. The total period of PTO delay in the processing of the patent application is therefore 501 days, which is equal to the "A delay" (318 days) plus the "B delay" (183 days).
- 294. Under 35 U.S.C. § 154(b)(2)(C), the applicable patent term adjustment "shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." The PTO determined that the period of applicant delay in the processing of the patent was 0 days.
- 295. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154(b) should have been 501 days.
- 296. On October 24, 2008, BMS filed a timely Request for Reconsideration of Patent Term Adjustment under 35 U.S.C. § 154(b)(3)(B)(ii) and 37 C.F.R. § 1.705(d). The request demonstrated that in light of the *Wyeth* decision, the proper period of patent term adjustment was 501 days. The PTO denied that request on May 12, 2009.

297. The PTO's determination of the patent term extension for the '040 patent—in both its initial determination and in its denial of the Request for Reconsideration—was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A).

Prayer for Relief

WHEREFORE, Plaintiffs pray that this Court:

- 1. Issue an Order changing the period of patent term adjustment for the '991 patent to 549 days and requiring Defendant to alter the term of the '991 patent to reflect the changed adjustment.
- 2. Issue an Order changing the period of patent term adjustment for the '211 patent to 205 days and requiring Defendant to alter the term of the '211 patent to reflect the changed adjustment.
- 3. Issue an Order changing the period of patent term adjustment for the '372 patent to 893 days and requiring Defendant to alter the term of the '372 patent to reflect the changed adjustment.
- 4. Issue an Order changing the period of patent term adjustment for the '496 patent to 888 days and requiring Defendant to alter the term of the '496 patent to reflect the changed adjustment.
- 5. Issue an Order changing the period of patent term adjustment for the '713 patent to 876 days and requiring Defendant to alter the term of the '713 patent to reflect the changed adjustment.

- 6. Issue an Order changing the period of patent term adjustment for the '712 patent to 854 days and requiring Defendant to alter the term of the '712 patent to reflect the changed adjustment.
- 7. Issue an Order changing the period of patent term adjustment for the '562 patent to 654 days and requiring Defendant to alter the term of the '562 patent to reflect the changed adjustment.
- 8. Issue an Order changing the period of patent term adjustment for the '835 patent to 392 days and requiring Defendant to alter the term of the '835 patent to reflect the changed adjustment.
- 9. Issue an Order changing the period of patent term adjustment for the '002 patent to 447 days and requiring Defendant to alter the term of the '002 patent to reflect the changed adjustment.
- 10. Issue an Order changing the period of patent term adjustment for the '678 patent to 884 days and requiring Defendant to alter the term of the '678 patent to reflect the changed adjustment.
- 11. Issue an Order changing the period of patent term adjustment for the '196 patent to 635 days and requiring Defendant to alter the term of the '196 patent to reflect the changed adjustment.
- 12. Issue an Order changing the period of patent term adjustment for the '808 patent to 720 days and requiring Defendant to alter the term of the '808 patent to reflect the changed adjustment.

- 13. Issue an Order changing the period of patent term adjustment for the '373 patent to 474 days and requiring Defendant to alter the term of the '373 patent to reflect the changed adjustment.
- 14. Issue an Order changing the period of patent term adjustment for the '271 patent to 846 days and requiring Defendant to alter the term of the '271 patent to reflect the changed adjustment.
- 15. Issue an Order changing the period of patent term adjustment for the '267 patent to 471 days and requiring Defendant to alter the term of the '267 patent to reflect the changed adjustment.
- 16. Issue an Order changing the period of patent term adjustment for the '611 patent to 245 days and requiring Defendant to alter the term of the '611 patent to reflect the changed adjustment.
- 17. Issue an Order changing the period of patent term adjustment for the '604 patent to 540 days and requiring Defendant to alter the term of the '604 patent to reflect the changed adjustment.
- 18. Issue an Order changing the period of patent term adjustment for the '493 patent to 1,163 days and requiring Defendant to alter the term of the '493 patent to reflect the changed adjustment.
- 19. Issue an Order changing the period of patent term adjustment for the '063 patent to 637 days and requiring Defendant to alter the term of the '063 patent to reflect the changed adjustment.

- 20. Issue an Order changing the period of patent term adjustment for the '040 patent to 501 days and requiring Defendant to alter the term of the '040 patent to reflect the changed adjustment.
 - 21. Grant such further and other relief as this Court deems just and proper.

Respectfully submitted,

Dated: July 17, 2009

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